

Application Number 10/731,867  
Amendment Responsive to Office Action mailed August 12, 2005

### **REMARKS**

This amendment is responsive to the Office Action dated August 12, 2005. Applicant has amended claims 1, 7, 9, 13-17 and 23, and added new claims 28 and 29. Claims 1-29 are pending.

### **Claim Objections**

In the Office Action, the Examiner objected to claim 1 as previously presented because the word "flexible" in the phrase "the flexible overmold" lacked antecedent basis. The Examiner also objected to claim 3 under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, because claim recited "wherein the overmold is flexible. Applicant has amended claim 1 to remove the word "flexible," and believes that this amendment overcomes both the Examiner's objections. Accordingly, Applicant respectfully requests that both of these objections be withdrawn.

### **Claim Rejection Under 35 U.S.C. § 112**

In the Office Action, the Examiner rejected claims 14-17 as previously presented under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Examiner argued that the phrase "the module" in each of these claims lacked adequate antecedent basis because claim 13, from which each of claims 14-17 depends, recites multiple modules. Applicant notes that claim 13 also recites "at least one of the modules." Applicant has amended claims 14-17 to recite "the at least one of the modules" for purposes of clarification. Applicant submits that claims, as amended, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. § 112, second paragraph.

### **Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 1-9, 11-13 and 18-27 under 35 U.S.C. § 103(a) as being unpatentable over US 6,308,101 to Faltys et al. (Faltys) in view of US 2003/0004546 by Casey (Casey), and rejected claims 10 and 14-17 under 35 U.S.C. § 103(a) as being unpatentable over Faltys in view of Casey and US 6,358,281 to Berrang et al. (Berrang).

Application Number 10/731,867  
Amendment Responsive to Office Action mailed August 12, 2005

Applicant respectfully traverses these rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

*Claims 1-22*

For example, Faltys and Casey fail to teach or suggest an implantable medical device comprising a plurality of interconnected modules, each of the modules comprising a respective one of plurality of housings, and an overmold that at least partially encapsulates each of the housings, as required by independent claim 1, as amended. The Examiner relied on Faltys as teaching both of these requirements of claim 1.

In general, Faltys discloses alternative embodiments for facilitating transmission of data and power between two modules of a cochlear implant system. One embodiment, referred to as the "wired system," includes a cable that connects the two modules for transmission of data and power between the modules.<sup>1</sup> Another embodiment, referred to as the "proximity system," includes coils for inductive transfer of data and power between modules instead of a cable.<sup>2</sup> More particularly, in the proximity system embodiments, one of the modules is electrically connected to an external coil, which may be encased in a silicone mold, and is positioned over a coil located inside of the other module.<sup>3</sup>

The Examiner cited the wired system embodiments of Faltys as teaching interconnected modules, as required by claim 1. The Examiner then cited the silicone mold from the proximity system embodiments as teaching an overmold, as required by claim 1. However, Faltys does not teach or suggest that a single device could include both the cable and the silicone mold and coil. Instead, Faltys teaches that these features are alternatives that perform the same function, and that either, but not both, may be included in a device.

For example, with respect to the proximity system embodiments, Faltys states:

There is no direct electrical or physical connection between the first and second devices through which power and/or control signals are communicated from one device to the other. That is, there is no detachable cable that connects the two

<sup>1</sup> Faltys: FIGS. 1D, 1F and 6; col. 2, ll. 51-55; col. 9, ll. 7-16; col. 14, ll. 1-9.

<sup>2</sup> Faltys: FIGS. 1E, 3A and 3B; col. 3, ln. 62 – col. 4, ln. 17; col. 12, ll. 17-55.

<sup>3</sup> Faltys: FIGS. 3A and 3B; col. 12, ll. 32-41.

Application Number 10/731,867

Amendment Responsive to Office Action mailed August 12, 2005

devices together as is the case with the "wired system" embodiment. Rather, power and control signals are inductively (magnetically) coupled from the second device to the first device...<sup>4</sup>

Additionally, one of ordinary skill would have understood that inclusion of both a cable and a molded coil in a single device would have been redundant and therefore unnecessary, and therefore would not have been motivated to modify any of the devices taught by Faltys to include both features. Accordingly, Faltys does not teach or suggest an implantable medical device that includes both interconnected modules and an overmold, as required by independent claim 1. Further, Casey provides no teaching that would overcome this deficiency of Faltys with respect to the requirements of Applicant's claims.

The applied references also fail to teach or suggest an implantable medical device comprising an overmold that is formed such that a surface of the overmold that is proximate to a cranium of a patient when the implantable medical device is implanted on the cranium is concave along at least one axis, which is also required by amended independent claim 1. The Examiner acknowledged that Faltys fails to teach or suggest this requirement of claim 1. Instead, as illustrated in FIGS. 3A and 3B, Faltys discloses a mold for a coil 174 that has flat surfaces.

The Examiner found that Casey discloses a number of photocells laminated together in the shape of a gradual curve that duplicates the curvature of the cranium at the implantation site, i.e., behind the ear as illustrated in FIG. 4 of Casey. The Examiner then argued that it would have been obvious to modify devices taught by Faltys such that the mold 174 was concave along at least one axis to conform to the cranium. Applicant respectfully disagrees.

Casey teaches that it is desirable for a group of photocells to be laminated together in the shape of a curve to match the surface they will be in contact with when implanted – the cranium behind the ear. However, this teaching is irrelevant in the context of the mold 174 of the device described by Faltys. As clearly illustrated in FIG. 3A of Faltys, the surface of mold 174 proximate to the cranium when implanted contacts the flat surfaces of the housings of modules 162 and 112'. Accordingly, even when considering Casey, one of ordinary skill would not have been motivated to modify mold 174 to have a concave surface proximate to the cranium, as required by claim 1.

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<sup>4</sup> Faltys: col. 4, ll. 1-9.

Application Number 10/731,867

Amendment Responsive to Office Action mailed August 12, 2005

For this reason, one of ordinary skill would also not have been motivated to modify mold 174 to conform substantially to the cranium, as required by claim 6. Again, mold 174 does not contact the cranium, and instead contacts the flat surfaces of modules 162 and 112'.

As another example, claim 7 requires that the surface of the overmold conforms substantially to an arc, and the radius of the arc is within a range from 4.5 to 9.5 centimeters. Claim 8 requires that the radius of the arc is approximately equal to 7 centimeters. Neither Faltys nor Casey teaches or suggests these requirements of claims 7 and 8.

Nonetheless, relying on holdings of the Federal Circuit, the Examiner argued that it would have been obvious for to make mold 174 conform to such arcs because discovering optimum ranges or values of result effective variables involves only routine skill in the art. However, "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation."<sup>5</sup> The holdings on which the Examiner relies are based on optimization of a value or range disclosed in the prior art that is different from the claimed range or value.<sup>6</sup> Casey does not even discuss arcs or radii of curvature, much less provide a range or value for such measurements that one of ordinary skill could optimize. Accordingly, the holdings relied on by the Examiner are inapplicable to the present fact pattern.

As another example, the applied references fail to teach or suggest an implantable medical device as recited in claim 1 wherein the overmold completely encapsulates each of the modules, as required by claim 11. The Examiner acknowledged that the combination of Faltys and Casey fails to teach or suggest this requirement, but nonetheless argued that it would have been obvious to further modify the combination such that the mold completely encapsulated both of the modules 162 and 112' of the Faltys device. Applicant respectfully disagrees.

The motivation cited by the Examiner, "to improve the device's ability to fit to the curvature of the cranium," is found nowhere in the prior art of record. None of the applied references teaches or suggests that the degree of encapsulation has any relevance or relationship to the ability to fit to the curvature of the cranium. The Court of Appeals for the Federal Circuit

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<sup>5</sup> *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); *see also* MPEP 2144.05.

<sup>6</sup> *See* MPEP 2144.05

Application Number 10/731,867  
Amendment Responsive to Office Action mailed August 12, 2005

has made clear that motivation to combine references must be found in the prior art, and that it is impermissible hindsight for the Examiner to use the motivation stated in Applicant's own disclosure as a blueprint to reconstruct the claimed invention from the prior art.<sup>7</sup>

Moreover, completely encapsulating both of modules 162 and 112' of the Faltys device in module 174 would entirely eliminate one of the significant advantages that Faltys teaches is provided by that device. In particular, Faltys teaches that the modules are advantageously separately implantable and explantable, to allow for individual replacement and upgrade of the modules.<sup>8</sup> One of ordinary skill would have recognized that completely encapsulating both modules in the mold would prohibit individual implantation and explantation. Accordingly, one of ordinary skill would have consciously avoided modifying Faltys in the manner suggested by the Examiner.

As another example, claims 19 and 20 require that a surface of one of the module housings conforms substantially to an arc with a radius within a range from 4.5 to 9.5 centimeters, or is approximately equal to 7 centimeters, respectively. As was the case for claims 7 and 8, the Examiner relies on holdings relating the general motivation to optimize values or ranges. For the reasons discussed above with reference to claims 7 and 8, these holdings are inapplicable to the present fact pattern.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-22 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

#### *Claims 23-27*

Independent claim 23 requires an implantable medical device housing including a surface proximate to a cranium that is concave along at least one axis such that the surface conforms substantially to an arc with a radius within a range from 4.5 to 9.5 centimeters. Claim 24 further requires that the arc is substantially equal to 7 centimeters. The Examiner acknowledged that the applied references fail to disclose or suggest these requirements of claims 23 and 24.

<sup>7</sup> See *Interconnect Planning Corp. v. Feil*, 227 USPQ 543 (CAFC 1985); see also *In re Fine*, 5 USPQ2d 1596, 1598 (CAFC 1988); see also *In re Gorman*, 18 USPQ 2d 1885, 1888 (CAFC 1991); see also *Al-Site Corp. v. VSI International, Inc.*, 50 USPQ2d 1161, 1171 (CAFC 1999).

<sup>8</sup> Faltys: col. 3, ll. 51-61; col. 4, ll. 11-17; col. 4, ln. 56 – col. 5, ln. 7.

Application Number 10/731,867

Amendment Responsive to Office Action mailed August 12, 2005

Nonetheless, relying on holdings of the Federal Circuit, the Examiner argues that it would have been obvious for one of ordinary skill to optimize the device of Casey to the claimed range and value.

However, as stated above with reference to claims 7 and 8, the holdings on which the Examiner relies are based on optimization of a value or range disclosed in the prior art that is different from the claimed range or value.<sup>9</sup> Casey does not even discuss arcs or radii of curvature, much less provide a range or value for such measurements that one of ordinary skill could optimize. Accordingly, the holdings relied on by the Examiner are inapplicable to the present fact pattern.

Because the holdings are inapplicable, the Examiner must meet his burden of establishing a prima facie case of obviousness by identifying some teaching or suggestion of the identified requirements of claims 23 and 24 in the prior art. As acknowledged by the Examiner, there is no teaching or suggestion of these requirements within the applied references. For at least that reason, the Examiner has failed to establish a prima facie case of obviousness of claims 22-27.

Additionally, as amended, independent claim 23 requires that the housing is metallic. Further, claim 27 requires control electronics and therapy delivery circuitry within the housing. The applied references fail to teach or suggest these requirements.

The Examiner acknowledged that the rigid metallic and ceramic housings disclosed by Faltys are not concave, but argued that it would have been obvious to make such housings concave in view of the teachings of Casey. However, in contrast to these requirements of Applicant's claims, Casey teaches housing curvature only with respect to a group of photocells, rather than control electronics or therapy delivery circuitry, and a flexible plastic laminate, rather than a metallic housing. In conjunction with the photocells, Casey also discloses an implanted amplifier 160, which is likely more similar to the Faltys devices than the photocells.<sup>10</sup> However, Casey does not suggest that the amplifier 160 has a curved housing to conform to the cranium, and instead teaches that the amplifier is recessed into the cranium. Accordingly, one of ordinary skill would not have been motivated by the teachings of Casey to make the rigid housings disclosed by Faltys curved.

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<sup>9</sup> See MPEP 2144.05

<sup>10</sup> Casey: paragraph [0043].

Application Number 10/731,867  
Amendment Responsive to Office Action mailed August 12, 2005

For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness of claims 23-27. Applicant respectfully requests that these rejections be withdrawn.

**New Claims:**

Applicant has added claims 28 and 29 to the pending application. Both claims depend from independent claim 1, and are allowable for at least the reasons stated above with respect to claim 1. Additionally, the applied references fail to disclose or suggest the limitations recited by the new claims. As one example, the references fail to disclose two metallic housings. Faltys, for example, discloses that one of the housings of its device is ceramic to facilitate inductive communication between the modules.<sup>11</sup> No new matter has been added by the new claims.

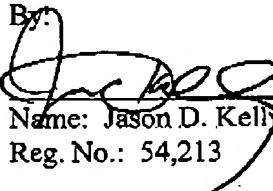
**CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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12-12-05  
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<sup>11</sup> Faltys: col. 12, ll. 21-25.